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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/482,785	06/07/1995	CRAIG W. ADAMS	30429.39US02	2723

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/482,785

Applicant(s)

ADAMS ET AL

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12, 18, 26, 47-50 and 64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6-8, 11, 18, 26 and 47-50 is/are rejected.
- 7) ☒ Claim(s) 3, 5, 9 and 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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DETAILED ACTION

This application has been returned to the examiner in light of the decision of the Board of Patent Appeals and Interferences.

Claims 1-9, 11-12, 18, 26, 47-50 and 64 are pending in the instant application.

The rejections set forth in the previous office action mailed December 28, 1995 are withdrawn.

The following new grounds of rejection are applied to the claims:

Claim Objections

1. Claims 1, and 3 are objected to because of the following informalities: Claims 1 and 3 each refer to the amino acid sequence of a "Figure." To fully comply with the sequence requirements, Applicants are required to recite a SEQ ID NO associated with the claimed sequence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 1-2, 4, 6-8, 11, 18, 26 and 47-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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Claims 1-2, 4, 6-8, 11, 18, 26, and 47-50 recite sequences encoding a “functional equivalent” of *S. pyogenes* Dnase B enzyme, as well as “at least one sequence from bacteriophage λ ” and to *S. pyogenes* promoters of undefined structure.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, “functional equivalent or at least one sequence” is insufficient to describe the genus.

One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Applicant is reminded that *Vas-Cath* make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus.

The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "functional equivalent." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what level of identity is required to be considered equivalent? Similarly at what level is the divergence so great as to not be considered an equivalent? Furthermore, what function is being measure for equivalence, (e.g., identity, enzymatic activity, etc.)? Without a clear definition as to the metes and bounds of the term "functional equivalent" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

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4. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "homologous." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what level of identity is required to be considered homologous? Similarly at what level is the divergence so great as to not be considered homologous? Without a clear definition as to the metes and bounds of the term "homologous" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

5. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "derived." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what level modification is being done as recited by the term "derived." Without a clear definition as to the metes and bounds of the term "derivative" there is no way to identify the metes and bounds of the claimed invention.

As a suggestion, amendment of the claim to recite "obtained from" will be sufficient to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-2, 4, 6-8, 11, 18, 26, and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Frenz et al.

The claims are directed to substantially purified DNA comprising DNA encoding an amino acid sequence selected from the group consisting of *Streptococcus pyogenes* Dnase B enzyme as shown in Figure 4 and a sequence encoding a functional equivalent of *S pyogenes* Dnase B enzyme.

Frenz et al (US Patent Number 5,279,823) disclose of the successful cloning and expression of human Dnase in recombinant host cells. (See column 6).

Given that the DNA disclosed by Frenz et al has the same activity as that disclosed by Applicants (Dnase), the disclosure of Frenz et al is deemed to anticipate the functional equivalent language of the claims.

7. Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by Birkett et al.

The claim is directed to a single stranded nucleic acid probe hybridizing with the DNA sequence coding for the amino terminal 23 amino acids of the *Streptococcus*

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pyogenes Dnase B enzyme, not including any portion of the leader sequence thereof, with no greater than about a 30% mismatch.

Birkett et al (US Patent 5,302,527) disclose of isolated random hexamer nucleic acids contained within a multiprime kit. (See column 15).

In view that the random hexamer kit disclosed by Birkett et al contains isolated single stranded nucleic acid probes which will hybridize to the sequences of the instant invention, the disclosure of Birkett et al is deemed to anticipate the claimed invention.

Claims 3, 5, 9, and 12 are objected to for depending upon a rejected base claim, however claims 3, 5, 9 and 12 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
February 22, 2004